

## REMARKS

### I. PRELIMINARY REMARKS

Claims 52 and 68 have been amended. Claim 108 has been canceled. Claims 109-112 have been added. Claims 45, 47, 48, 50-54, 65, 68-71, 73-81, 83-87, 89, 90, 92-96, 99-107 and 109-112 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Claims 45, 71, 75-79, 95, 96, 101 and 104 have been allowed.

Claim 52 has been re-written to call for the combination previously presented in now-canceled claim 108. The amendment to claim 68 merely corrects a clear error, i.e., the double recitation of tear prevention, that was introduced in the prior amendment.

### II. REQUEST FOR WITHDRAWAL OF THE FINALITY OF THE OFFICE ACTION

Claims 47, 48, 50, 51, 53, 54, 80 and 81 were rejected under 35 U.S.C. § 102 as being anticipated by Hammerslag in the Office Action dated July 2, 2010. On page 3, the July 2, 2010 Office Action explained that the Hammerslag attachment 28, which is “a solder, braze or weld joint,” corresponded to the claimed “anti-tear device.” Applicant’s subsequent response to the Office Action, which did not include amendments to claim 47 or the presentation of claims dependent thereon in an attempt to establish a “middle ground,” was based on this explanation. The outstanding Final Office Action also rejected Claims 47, 48, 50, 51, 53, 54, 80 and 81 under 35 U.S.C. § 102 based on Hammerslag. Here, however, the Examiner indicated that a portion of the Hammerslag spring coil 14 corresponds to the claimed “anti-tear device.” [OA at p. 3.] Applicant respectfully submits that this fundamental change in the manner in which “anti-tear device” and Hammerslag are being interpreted constitutes a new ground of rejection which was not necessitated by an amendment and, therefore, that the finality of the outstanding Office Action should be withdrawn. [See MPEP § 706.07(a).]

### III. REJECTION UNDER 35 U.S.C. § 102 BASED ON HAMMERSLAG

#### A. The Rejection

Claims 47, 48, 50, 51, 53, 54, 68, 80, 81, 89 and 90 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,378,234 to Hammerslag ("Hammerslag"). The rejection under 35 U.S.C. § 102 is respectfully traversed. Reconsideration thereof is respectfully requested.

#### B. Hammerslag

Referring to Figures 1 and 2, Hammerslag discloses a steerable sheath 10 that includes a spring coil 14, an end cap 20, and a pull ribbon 34 that deflects the spring coil. A deflection ribbon 26 is located along the inner surface of the distal portion of the spring coil 14 opposite the pull ribbon 34. The distal end of the deflection ribbon 26 is held between the inner surface of the spring coil 14 and the end cap 20. [Col. 4, ll. 61-63.] The proximal end of the deflection ribbon 26 is secured to the inner surface of the spring coil 14 by proximal attachment 28, which is "a solder, braze or weld joint." [Col. 4, l. 58 to col. 5, l. 5.]

#### C. Discussion Concerning Claims 47, 48, 50, 51, 53, 54, 80 and 81

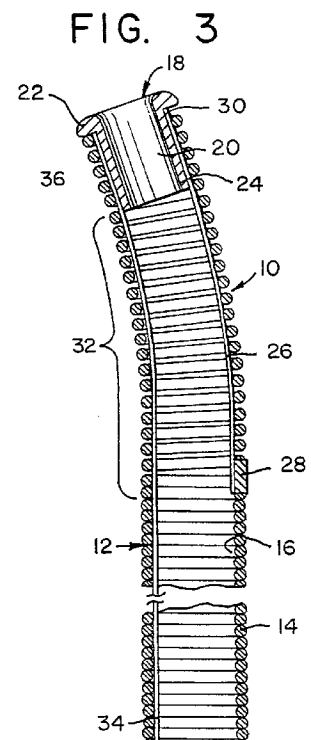
Independent claim 47 calls for a combination of elements including, *inter alia*, "an elongate body," "a stiffening member associated with the distal portion of the elongate body, "**an anti-tear device** positioned within the elongate body wall between the inner surface and the outer surface adjacent to at least a portion of the proximal half of the stiffening member and not adjacent to the distal half of the stiffening member, and **configured to prevent the stiffening member from tearing through the elongate body when the stiffening member bends**" and "a steering wire." The respective combinations defined by claims 48, 50, 51, 53, 54, 80 and 81 include, *inter alia*, the elements recited in claim 47.

Hammerslag fails to teach or suggest the claimed combinations. For example, the Office Action has taken the position that the Hammerslag deflection ribbon 26 and proximal attachment point 28 respectively correspond to the claimed “stiffening member” and the “anti-tear device.” [OA at p. 2.] Referring to Figure 2, applicant respectfully submits that one of skill in the art would recognize that the deflection ribbon 26 simply cannot tear through the spring coil 14. As such, there is no reasonable interpretation of “anti-tear device” that would encompass the attachment point 28, which is nothing more than the “solder, braze or weld joint” which secures the deflection ribbon 26 to the spring coil 14.

The Office Action made the following assertion in response to the argument above concerning the Hammerslag attachment point 28:

Since there are walls on either side of the coil member, it is possible that if not for the presence of the anti-tear device (28), the stiffening member's end could slip between the coils when the device is bent and tear through the walls of the elongate body.

[OA at p. 12.] There are a number of errors associated with this assertion. For example, when the pull ribbon 34 deflects the sheath in the manner illustrated in FIG. 3, the deflection ribbon 26 is urged radially outwardly (to the right in FIG. 3). Thus, even if the attachment point 28 fails, the deflection ribbon 26 will not move toward (or through) the inner wall. The coil 14 will, of course, prevent the deflection ribbon 26 from reaching the outer wall. Thus, the attachment point 28 does not prevent tearing. With respect to the “slip between the coils” conjecture, there does not appear to be any way for the deflection ribbon 26 to pass between the coils, whether or not the attachment point 28 fails. The coils are tightly wound at the proximal-most end of the deflection ribbon 26. Moreover, the Office Action appears to be taking the position that the proximal tip end of the deflection ribbon 26 will, if separated from the attachment point 28, spontaneously bend ninety degrees in the radially outward direction so that it could somehow poke through the coils (tight winding notwithstanding) and then through the outer wall. Applicant respectfully submits that this assertion is utterly unsupportable and



notes for the record that “anticipation of a claimed product ***cannot be predicated on mere conjecture*** as to the characteristics of a prior art product.” *Ex parte Standish*, 10 USPQ2d 1454, 1457 (Bd. Pat. App. & Int. 1988).

The Office Action also asserted in the context of claim 47 that “the body not only includes spring 14 but the inner and outer walls described above” and then, in the context of claims 50 and 51, asserted that “the anti-tear device could also be interpreted as including **member 14** which 28 is joined to.” [OA at p. 3.] In other words, the Office appears to have asserted that the spring coil 14 and attachment 28 together correspond to the claimed “anti-tear device.” This assertion is fundamentally flawed because claim 47 indicates that the “anti-tear device [is] not adjacent to the distal half of the stiffening member,” while the Hammerslag spring coil 14 extends over the entire length of the purported “stiffening member” (i.e., deflection ribbon 26). That issue notwithstanding, applicant hereby requests that the next Action:

1. Clarify whether or not the rejection of claim 47 is also based upon an interpretation that includes the coil spring 14 corresponding to the claimed “anti-tear device,” and
2. If the rejection is based upon the coil spring 14 corresponding to the claimed “anti-tear device,” explain how the portion of the coil spring 14 that is adjacent to the proximal half of the deflection ribbon 26 can be an “anti-tear device” while the portion of the coil spring 14 that is adjacent to the distal half of the deflection ribbon 26 is not an “anti-tear device.”

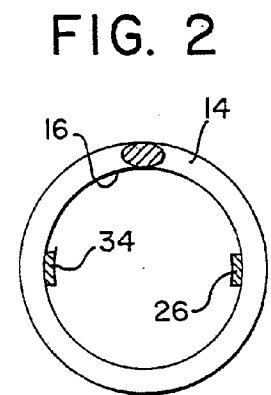
As illustrated above, Hammerslag fails to teach or suggest each and every element of the combination recited in independent claim 47. Applicant respectfully submits, therefore, that the rejection of claims 47, 48, 50, 51, 53, 54, 80 and 81 under 35 U.S.C. § 102 should be withdrawn.

#### D. Discussion Concerning Claims 68, 89 and 90

Independent claim 68 calls for a combination of elements including, *inter alia*, “an elongate body ... including a wall,” “a stiffening member,” and “**anti-tear means**, secured directly to the proximal portion of the stiffening member and located within the elongate body wall between the inner surface and the outer surface, **for preventing the stiffening member from tearing through the elongate body wall.**” The respective combinations defined by claims 89 and 90 include, *inter alia*, the elements recited in claim 68.

With respect to the interpretation of claim 68, the plain meaning of the word “tear” is “to make (an opening) by ripping: *tore a hole in my stocking.*” *The American Heritage® Dictionary of the English Language (2009)*. Thus, the claim calls for structure that performs the function of preventing the “stiffening member” from “making an opening in the elongate body wall by **ripping through** the elongate body wall.”

Hammerslag fails to teach or suggest the claimed combinations. For example, the Office Action has taken the position that the Hammerslag deflection ribbon 26 and proximal attachment 28 respectively correspond to the claimed “stiffening member” and the “anti-tear means.” [OA at p. 5.] Nothing in Hammerslag even remotely suggests that the attachment point 28, which is simply the “solder, braze or weld joint” that secures the deflection ribbon 26 to the spring coil 14, **performs the function** of preventing the deflection ribbon 26 from ripping through the spring coil 14 and/or the outer wall (not shown) discussed in column 6, lines 40-51. Referring to FIG. 2, applicant respectfully submits that one of skill in the art would recognize that the deflection ribbon 26 simply cannot rip through the spring coil 14. As such, the attachment point 28 does not inherently perform the claimed function of “preventing ... tearing.” Turning to the inner wall (not shown) discussed in column 5, lines 55-65, and as discussed in greater detail in the preceding section, the proximal end of the deflection ribbon 26 will not deflect toward the inner wall if the attachment point 28 fails.



Finally, with respect to the assertion regarding the proximal end of the deflection ribbon 26 somehow spontaneously bending and slithering through the coils, applicant respectfully submits, for the reasons noted in the preceding section, that this assertion is simply unsupportable conjecture and does not support an anticipation rejection.

As Hammerslag fails to teach or suggest each and every element of the combination recited in independent claim 68, applicant respectfully submits that the rejection of claims 68, 89 and 90 under 35 U.S.C. § 102 should be withdrawn.

### **III. REJECTION UNDER 35 U.S.C. § 102 BASED ON MATSUURA**

#### **A. The Rejection**

Claims 52, 83-86, 106, 107 and 108 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,450,948 to Matsuura ("Matsuura"). The rejection under 35 U.S.C. § 102 is respectfully traversed. Reconsideration thereof is respectfully requested.

Claim 52 has been re-written to call for the combination previously presented in now-canceled claim 108.

#### **B. Matsuura**

Matsuura discloses a variety of deflectable tips for use with steerable surgical instruments. The instrument illustrated in Figures 1-5 includes a deflectable tip section 40. The deflectable tip section 40 includes proximal and distal collars 50A and 50B on opposite ends of a flexible tubular body 52. A pair of strengthening members 54 are positioned within the wall of the tubular body 52 and extend from the end collar 50A to the end collar 50B. Turning to Figure 22E (next page), Matsuura also discloses the use of collars 1150A/1150B and ribbed strengthening members 1154A and 1154B.

Applicant also notes for the record that the arguments concerning Matsuura on page 18 of the prior amendment inadvertently reversed the distal/proximal locations of the collars. Given that the rejection was repeated, the error appears to have been harmless.

### C. Discussion Concerning Claims 52, 83-86, 106 and 107

Independent claim 52 calls for a combination of elements including, *inter alia*, “an elongate body,” “a steering wire,” “a stiffening member associated with the distal portion of the elongate body” and “a substantially c-shaped anti-tear device ... associated with the stiffening member such that a portion of the stiffening member is distal of the anti-tear device.” Claim 52 also indicates that the “stiffening member is substantially longer than the anti-tear device.” The respective combinations defined by claims 83-86, 106 and 107 include, *inter alia*, the elements recited in claim 52.

Matsuura fails to teach or suggest the claimed combinations. For example, and referring to Figure 22E, the Office Action has taken the position that the Matsuura collar 1150B corresponds to the claimed “stiffening member” and the strengthening members 1154A/B correspond to the claimed “anti-tear device.” [OA at p. 4.] In order to meet the “substantially longer than” limitation, the Office Action appears to have asserted that about 10% of the strengthening members 1154A/B is an “anti-tear device” while to other 90% is somehow non-existent or somehow not an “anti-tear device”. Specifically, on page 4, the Office Action argued in the context of now-cancelled claim 108 that:

[O]ne could interpret the anti-tear device as being the first segment of 1154a/b which is directly adjacent to 1150b. This segment, as seen in Fig. 22e, is shorter than 1150b. Therefore if one interprets the anti-tear device in

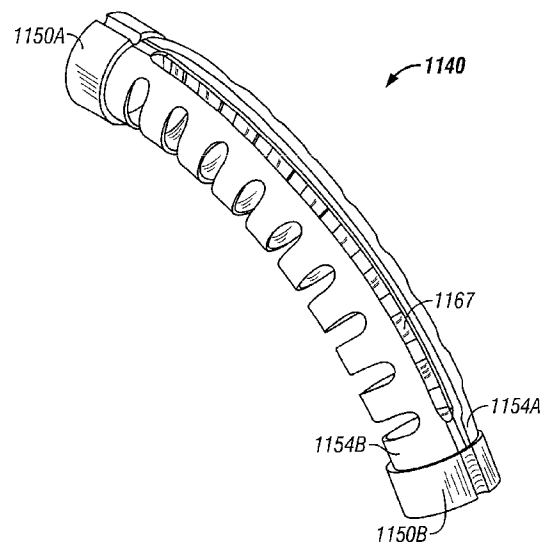


FIG. 22E

this manner, it can be said that the stiffening member (1150b) is longer than the anti-tear device.

Applicant respectfully submits that this argument is simply untenable. The ribbed strengthening members 1154A and 1154B are unitary structures that extend from collar 1150A to collar 1150B. The respective portions of each collar are not individual pieces. According to the reasoning presented in the Office Action, a basketball is substantially longer than a 7-foot tall basketball player if one “interprets” the basketball player to only be the portion between the soles of his feet and his ankles. Clearly, such reasoning is flawed and has no place in a rejection under 35 U.S.C. § 102.

As Matsuura fails to teach or suggest each and every element of the combination recited in independent claim 52, applicant respectfully submits that the rejection of claims 52, 83-86, 106 and 107 under 35 U.S.C. § 102 should be withdrawn.

#### **IV. REJECTION UNDER 35 U.S.C. § 102 BASED ON EBLING**

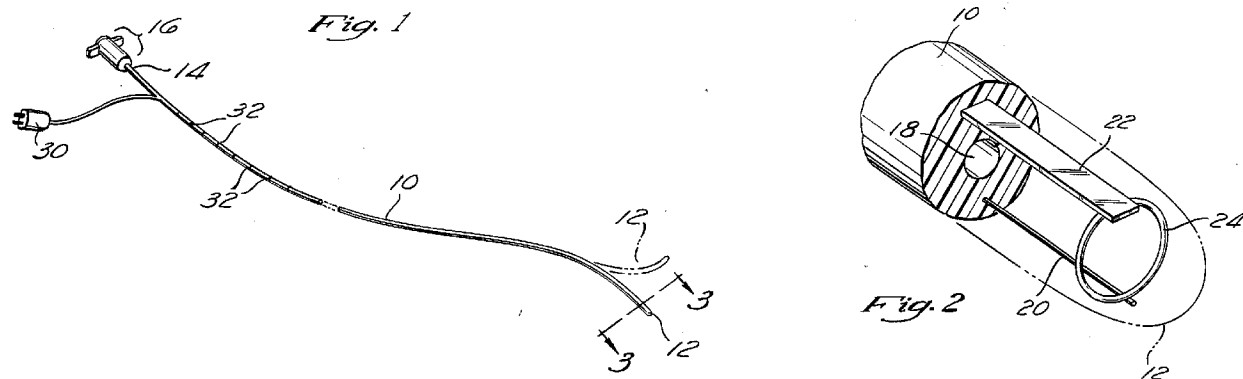
##### **A. The Rejection**

Claims 69, 70, 73, 74, 92-94, 99, 100, 102 and 103 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,934,340 to Ebling (“Ebling”). The rejection under 35 U.S.C. § 102 is respectfully traversed. Reconsideration thereof is respectfully requested.

##### **B. Ebling**

Referring to FIGS. 1 and 2 (following page), Ebling discloses device with a catheter 10 having a distal portion 12. A contractile wire 20, a bendable support member 22, and one or more connecting members 24, which “physically connect the bendable support member 22 to the contractile wire 20 so as to form a unitary ‘bending assembly’ or structure within the distal portion of the catheter,” are also provided. [Col. 4, ll. 1-5.]





### C. Discussion Concerning Claims 69, 73, 74, 92, 99 and 102

Independent claim 69 calls for a combination of elements including, *inter alia*, “**an elongate body defining** a longitudinal axis, a proximal portion and **a distal portion** and including a substantially solid single-piece wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion,” “a **steering wire**,” “an **anchoring member located within the distal portion** of the substantially solid single-piece **elongate body wall** between the inner surface and the outer surface and **secured to the steering wire**,” “a **stiffening member** [with a] distal end [that is] **directly secured to the anchoring member**” and “a **substantially tubular member** directly **secured to the stiffening member**.” Claim 69 also indicates that “the **steering wire is not connected to the substantially tubular member** ...” The combinations defined by claims 73, 74, 92, 99 and 102 include, *inter alia*, the elements recited in claim 69.

The Office Action has taken the position that the Ebling structures correspond to the elements recited in claim 69 in the following manner:

“steering wire” - Ebling contractile wire 20

“anchoring member” - Ebling connecting member 24

“stiffening member” - Ebling support member 22

“tubular member ... secured to stiffening member” - Ebling catheter 10

[OA at pp. 6 and 12.] There are a number of errors associated with this position. Most notably, the position taken in the Office Action failed to account for all of the elements in the

claim. If the Ebling catheter 10 corresponds to the claimed “tubular member,” then the Ebling device lacks the claimed “elongate body” in which the connecting member 24 (the purported “anchoring member”) is located. Faced with this clear shortcoming in Ebling, the Office Action also indicated that:

[T]he examiner is interpreting the tubular member which is secured to the stiffening member to be the tubular body of the device, as Applicant has not claimed that the tubular member must be a separate component.

[OA at p. 6.] In other words, the Office Action has taken the position that one of skill in the art, who had reviewed the present specification, would interpret the claimed “elongate body” and the claimed “tubular member ... secured to stiffening member” as possibly corresponding to the same structure. This position is simply incorrect. There is no “tubular member.”

Claim 69 also indicates that the “tubular member” is “directly secured” to the stiffening member” and that the “steering wire is not connected” to the substantially tubular member.” Nothing in Ebling indicates that the catheter 10 (the purported “tubular member”) is directly secured to the support member 22 (“the purported “stiffening member”). Like the contractile wire 20, the support member 22 is simply located within a lumen in the catheter 10. [See FIGS. 2 and 3.] Should the rejection be maintained, applicant hereby requests that the next Action explain, with reference to FIGS. 2 and 3, how Ebling can be reasonably interpreted such that the catheter 10 can be both (1) “not connected” to the contractile wire 20 and (2) “directly secured” to the support member 22.

As Ebling fails to teach or suggest each and every element of the combination recited in independent claim 69, applicant respectfully submits that the rejection of claims 69, 73, 74, 92, 99 and 102 under 35 U.S.C. § 102 should be withdrawn.

#### **D. Discussion Concerning Claims 70, 93, 94 and 100**

Independent claim 70 calls for a combination of elements including, *inter alia*, “an elongate body,” “a steering wire,” “an anchoring member,” “a stiffening member” and “a substantially tubular member,” including a slot through which the steering wire passes,

secured to the stiffening member.” The combinations defined by claims 93, 94 and 100 include, *inter alia*, the elements recited in claim 70.

Ebling fails to teach or suggest the claimed combinations. For example, and for the reasons discussed in the preceding section, if one were to take the position that the Ebling catheter 10 corresponds to the claimed “elongate body,” then the Ebling device lacks a “substantially tubular member including a slot.”

As Ebling fails to teach or suggest each and every element of the combination recited in independent claim 70, applicant respectfully submits that the rejection of claims 70, 93, 94 and 100 under 35 U.S.C. § 102 should be withdrawn.

## **V. REJECTION UNDER 35 U.S.C. § 103 BASED ON HAMMERSLAG, EBLING AND SAMSON**

### **A. The Rejection**

Claims 65 and 87 have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,378,234 to Hammerslag (“Hammerslag”), U.S. Patent No. 4,934,340 to Ebling (“Ebling”) and U.S. Pat. No. 5,695,483 to Samson (“Samson”). The rejection under 35 U.S.C. § 103 is respectfully traversed. Reconsideration thereof is respectfully requested.

### **B. Request For Clarification**

Applicant hereby requests that the next Action clarify, on a claim element by claim element basis, what the result of the combination of Hammerslag, Ebling and Samson actually is. By way of example, but not limitation:

1. What are elements of the Hammerslag, Ebling and Samson that constitute the “solid wall formed from a single material,” the “stiffening member” and the “anti-tear device” in the resulting device?
2. What portion of the Hammerslag device actually remains after the “obvious” modification thereto?

The arguments below are limited to “big picture” issues and based on applicant’s best guess as to the basis for the rejection. Additional arguments will follow the clarification if necessary.

### C. The Cited References

The disclosures of Hammerslag and Ebling are discussed above.

Samson discloses a “**composite device** having at least one section including a helically wound ribbon stiffener coaxially incorporated into that section or sections.” [Col. 4, ll. 33-36.] In other words, the wall of the Samson catheter consists of two materials.

### D. Discussion

Independent claim 65 calls for a combination of elements including, inter alia, “an elongate body defining a diameter, a proximal portion and a distal portion and including **a solid wall formed from a single material** defining an inner surface, an outer surface and a lumen defined by the inner surface extending from the proximal portion to an aperture in the distal portion,” “a steering wire having a distal portion that is located within the elongate body wall between the inner surface and the outer surface,” “a stiffening member” and “an **anti-tear device**, defining a proximal end and a distal end, secured directly to the proximal end of the stiffening member such that the proximal end of the anti-tear device is located within the distal portion of the elongate body wall between the inner surface and the outer surface.” The combination defined by claim 87 includes, inter alia, the elements recited in claim 65.

At the outset, applicant notes that the plain meaning of the word “single” is “consisting of one in number.” *The American Heritage® Dictionary of the English Language* (2009). As such, one of skill in the art would understand that the word “single” in claim 65 serves as a negative limitation which limits the claimed wall to **no more than one material**. As such, the Samson composite device teachings do appear to be applicable to claim 65.

Based on applicant's best guess, the rejection appears to contemplate modifications of the Hammerslag device that would somehow result in the elimination of spring coil 14 and the use of a "solid wall formed from a single material" in its place. Applicant respectfully submits that such a modification would not have been obvious because it would fundamentally change the operational principle of the Hammerslag device. The Hammerslag device is, at its most fundamental level, a device with coil-based distal portion. [See, e.g., col. 10, ll. 56-68.] Turning the Hammerslag device into a "no-coil, solid one material wall" device would not have been obvious.<sup>1</sup>

As the cited references to establish a *prima facie* case of obviousness of the combination recited in independent claim 65, applicant respectfully submits that the rejection of claims 65 and 87 under 35 U.S.C. § 103 should be withdrawn.

## **VI. NEWLY PRESENTED CLAIMS 109-112**

Newly presented claim 109 depends from independent claim 47 and is patentable for at least the same reasons as claim 47.

Newly presented claim 110 depends from independent claim 52 and is patentable for at least the same reasons as claim 52.

Newly presented claim 111 depends from independent claim 69 and is patentable for at least the same reasons as claim 69.

Newly presented claim 112 depends from independent claim 70 and is patentable for at least the same reasons as claim 70.

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<sup>1</sup> See MPEP § 2143.01-VI ("if the proposed modification or combination of the prior art would **change the principle of operation** of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious").

## VII. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

February 25, 2011  
Date

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